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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,078	02/08/2006	Leslie Philip Miranda	AMLN-044	4061

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EXAMINER
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BRADLEY, CHRISTINA

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/541,078

Applicant(s)

MIRANDA ET AL.

Examiner

Christina Marchetti Bradley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/20/2006.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.
3. Claims 1-28, 45-52, 54 and 56-59 are drawn to water-soluble thioester or selenoester compounds comprising an amino acid synthon which comprises an N- and C-terminal group joined by an organic backbone wherein the C-terminal group is joined to a water-soluble polymer through a thioester or a selenoester. The specification only discloses the complete structure of the peptide GFRN 1852-PLP<sub>3</sub>-Leu shown with its generator compound in example 5 and the partial structure of a subset of the genus, the formula in claim 29 to which claims 29-44, 53 and 55 are drawn. With the exception of GFRN 1852-PLP<sub>3</sub>-Leu, this genus is exceptionally broad. The minimal structural requirements for the genus are an N- and C-terminal group joined

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by a an organic backbone and a thioester or selenester linking a water soluble polymer to the C-terminal group. An infinite number of compounds could satisfy these minimal requirements. Even the formula recited in claim 29 could be satisfied by an infinite number of compounds considering that the side chains are limited only to organic side chains and can appear in any order or sequence. In addition, claims 29-44, 53 and 55 are drawn to "a target molecule of interest". The specification fails to define a complete or partial structure or any distinguishing characteristics for this genus. Claim 56 is also drawn to "a compound of interest." The specification likewise fails to define a complete or partial structure or any distinguishing characteristics for the "compound of interest" genus. Finally, claim 57 is drawn to chemical ligation of two components. Again, the specification fails to define a complete or partial structure or any distinguishing characteristics for the "component" genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

4. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). With the exception of GFRN 1852-PLP<sub>3</sub>-Leu, the skilled artisan cannot envision the detailed chemical structure of the thioester or selenoester compound. Although the minimal structural requirements of the broad genus are defined, there are too many undefined structural features to place the public in possession of the full scope of the claims. Therefore, only GFRN

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1852-PLP<sub>3</sub>-Leu, but not the full breadth of the claims, meet the written description provision of 35 U.S.C. §112, first paragraph.

5. Applicant's arguments, filed 12/13/2006, with respect to claim 16, 45-53 and 56 have been fully considered and are persuasive. The rejection of claims 16, 45-53 and 56 under 35 U.S.C. 112, second paragraph has been withdrawn.

***Claim Rejections - 35 USC § 102***

6. Applicant's arguments, filed 12/13/2006, with respect to the rejection(s) of claim(s) 1, 2, 5, 6, 11-14, 20-22, 26-31, 34, 36-39, and 41-44 under 35 U.S.C. 102(b) have been fully considered and are persuasive in light of the amendment to the claims. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 5, 6, 11-14, 20-22, 26-31, 34, 36-39, 41-44 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Sasaki & Koga (*J. Inclus. Phen. Mol. Recog. Chem.*, **1989**, 7, 267-76). Sasaki & Koga teach a dipeptide and tetrapeptide wherein the N-terminal amino group is protected and the C-terminal group is joined to a water-soluble polymer through a thioester (see Scheme 2, compound 9 which is further defined on page 269). Compounds 12 and 13 which substitute for the crown ether in compound 9 have molecular weights greater than 500 Daltons. Regarding claims 14 and 34, the water-soluble polymer comprises one or more

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alkylene oxide moieties. Regarding claims 20, 36 and 37, the thioester is sterically hindered.

Regarding claims 21, 22, 38 and 39, the water-soluble polymer is joined to the thioester through a linker comprising a divalent radical. Regarding claims 26-28 and 41-44, the compound is monodisperse.

9. Claims 1-3, 5-8, 11-13, 20, 26-29, 32, 36, 37, 41-44 and 58 are rejected under 35

U.S.C. 102(b) as being anticipated by Baca *et al.* (*J. Am. Chem. Soc.*, **1995**, *117*, 1881-7). Baca *et al.* teach a 51 residue peptide comprising an N-terminal group and C-terminal group wherein the C-terminal group is linked to a water-soluble polymer (another polypeptide) by a thioester (see compound 10 in Figure 3). Regarding claims 7, 8, and 32, the N-terminal group comprises an amino acid residue and a sulfur moiety that is capable of supporting chemical ligation.

Regarding claims 20, 36 and 37, the thioester is sterically hindered. Regarding claims 26-28 and 41-44, the compound is monodisperse.

### Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Marchetti Bradley, Ph.D.

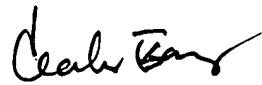
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Patent Examiner  
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